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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/936,170

02/01/2002

Tse Wai-Choi Eric

109312.

9703

7590 02/22/2008
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EXAMINER

GABEL, GAILENE

ART UNIT

PAPER NUMBER

1641

MAIL DATE

DELIVERY MODE

02/22/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/936,170

Applicant(s)

ERIC ET AL.

Examiner

GAILENE R. GABEL

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,5,7-11 and 14-18 is/are pending in the application.
- 4a) Of the above claim(s) 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,5, 7-11, 14-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1,4,5 and 7-18 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 31, 2007 has been entered.

Amendment Entry

2. Applicant's amendment and response filed on October 31, 2007 is acknowledged and has been entered. Claim 1 has been amended. Claims 12 and 13 have been cancelled. Claim 18 remains withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Accordingly, claims 1, 4, 5, 7-11, and 14-18 are pending. Claims 1, 4, 5, 7-11, and 14-17 are under examination.

Withdrawn Rejections

3. All rejections and objections not reiterated herein, have been withdrawn.
4. The rejections of claims 12 and 13 are now moot in light of Applicant's cancellation of the claims.

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5. In light of Applicant's amendment and arguments, the rejection of claims 1, 4, 5, and 7-17 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is hereby, withdrawn.

6. In light of Applicant's amendment and arguments, the rejection of claims 1, 4, 5, 7-11, and 14-17 under 35 U.S.C. 102(b) as being anticipated by Gargano et al. (From Phage Libraries to Intracellular Immunization, Intracellular Antibodies: Development and Applications (1997) Chapter 10, pages 174-186)), is hereby, withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1, 4, 5, 7-11, and 14-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, in steps c) and d), is indefinite in failing to recite a positive limitation in the claim in reciting, "to produce a detectable reporter molecule" in step c) and "detecting said detectable reporter molecule", and "detection is indicative of binding" in step d)" because it appears that the "detectable reporter molecule", albeit detectable, requires a signal to be produced so as to allow detection of binding as required by the preamble. Based on substantial teaching in the specification, by failing to recite a positive limitation in the claim in regards to the "detectable reporter molecule", it appears that actual binding between immunoglobulin and target cannot be measured and determined, to meet the requirement of the preamble.

The following language is suggested but not required in obviating this indefiniteness rejection:

- c) ... wherein binding of said immunoglobulin and said target brings said first molecule and said second molecule into operative association such that association of the immunoglobulin to the target leads to a stable interaction between the first molecule and the second molecule; thus producing a detectable reporter molecule that generates a signal; and
- d) detecting said signal from said detectable reporter molecule, wherein detection of a signal is indicative of binding between said immunoglobulin and said target in the intracellular environment.-

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Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1, 4, 5, 7-11, and 14-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabled for determining binding of an immunoglobulin to a target in an intracellular environment whereupon first and second molecules fused thereto are brought into operative association which leads to a stable interaction therebetween to produce a detectable reporter molecule that generates a signal, does not reasonably provide enablement for the method whereupon the first and second molecules fused thereto are brought into operative association, but does not lead to a stable interaction between the first molecule and the second molecule to allow production of a detectable reporter molecule that generates a signal. The specification does not enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

As set forth in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988), enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include 1) the nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the quantity of experimentation necessary, 7) the relative skill of those in the art, and 8) the breadth of the claims.

The specification does not disclose, nor provide sufficient guidance for determining binding of immunoglobulin to a target in an intracellular environment as claimed, wherein upon expression of the first fusion polypeptide together with the second fusion polypeptide and binding of the immunoglobulin to the target, the first molecule and the second molecule are brought into operative association, which produces a detectable reporter molecule, BUT does not lead to a stable interaction between the first molecule and the second molecule and generation of a signal. Page 3, line 11 to page 12, line 4; page 5, lines 1-25; page 6, lines 7-14; and page 23, lines 4-8 of Applicant's disclosure provide that a stable interaction between the first molecule and the second molecule and the generation of a signal that results to a positive outcome, is a requirement for the method to be work. The immunoglobulins that cause a signal to be generated in the intracellular environment are those that are then selected and screened (page 4, lines 25-28). The transcription units encoding the immunoglobulins fused to signal generating molecules and which result to generation of a signal are selected based on their capability of functioning intracellularly (page 7, lines 11-29; page 26, lines 10-15; and page 28, line 27 to page 29, line 29). Accordingly, in the absence of further

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guidance from Applicant as well as working examples in the specification which describe a method of determining binding of immunoglobulin and target in an intracellular environment, which does not require that a stable interaction between a first molecule and a second molecule is resulted so as to result to generation of a signal, one of ordinary skill in the art would not be assured of the ability to perform the instant method, as claimed.

Response to Arguments

9. Applicant's arguments filed on October 31, 2007 are now moot in light of the new grounds of rejection.

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GAILENE R. GABEL whose telephone number is (571)272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 8:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GAILENE R. GABEL/
Primary Examiner, Art Unit 1641

February 15, 2008